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Docket No. CRD-884

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Robert E. Fischell et al.

Serial No. : 09/609,163

Art Unit: 3739

Filed : June 30, 2000

Examiner: Vy Bui

For ~~3739~~ 3739 STENT WITH IMPROVED FLEXIBLE CONNECTING LINKS

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(Date)

Paul A. Coletti

Name of applicant, assignee, or registered representative

(Signature)

September 25, 2002

(Date of Signature)

Commissioner for Patents
Washington, D.C. 20231

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TECHNOLOGY CENTER R3700

APPEAL BRIEF

Dear Sir:

06/11/2003 DBROOKS 00000002 100750 09609163
01 FC:1402 The following represents the party Cordis Corporation's,
Appeal Brief in the above-captioned application.

I. Real Party in Interest

The real party in interest in this application is CORDIS CORPORATION, the owner of the current patent application.

II. Related Appeals and Interferences

There are no related appeals or interferences associated with the current application.

III. Status of the Claims

The claims have been finally rejected in an Office Action dated February 26, 2002.

IV. Status Of Amendments

There have been no amendments filed subsequent to the final rejection.

V. Summary of the Invention

The current invention is a vascular stent comprising sets of strut members connected by flexible links. This design uses a script "N" shaped flexible link instead of the "S" link described by Fischell et al. in U.S. Patent 5,69,971. The "N" links, instead of touching or overlapping during crimping, are designed to nest one into the other, allowing the stent to crimp down without overlap onto a low profile balloon. The "N" links are attached to the strut members not at the center of the strut member, like the "S" links in the prior art, but off-center near the end of the curved end strut portion of each strut member. This off center attachment point allows for a more flexible link without increasing the cell size of the expanded stent. Small cell size is desirable to limit plaque prolapse into the lumen of

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the expanded stent. To enhance flexibility, the width of the "N" should be less than 0.10 mm.

An alternate embodiment of the flexible stent is also envisioned, where the "N" link has certain curved segments to further minimize stent cell size or to use "M"-shaped or "W"-shaped links, each having additional undulations as compared to the "N" link.

VI. Issues on Appeal

There are three issues on appeal. First, are claims 50 and 53-54 unpatentable under 35 USC §103(a) as obvious over the Hess, et al. reference, WO98/40035 ("Hess"), taken alone?

Second, are claims 50 and 51 unpatentable as obvious under 35 USC §103(a) using Hess in view of Richter, US Patent 5,807,404 ("Richter")?

Third, are all the claims obvious under 35 USC §103(a) as unpatentable over Richter in view of Hess?

VII. Grouping of Claims

It is believed that because each of the claims is rejected exclusively under the obviousness statute, 35 USC §103, that each of the claims stands or falls separately from all the other claims. Accordingly, claims 50, 51, 52, 53 and 54 are to be examined separately using each of the relevant rejections.

VIII. Argument

A. Are claims 50 and 53-54 obvious under 35 USC §103(a) using Hess?

The Examiner first uses Hess to reject claims 50 and 53-54. According to the Examiner, the stent in Figure 4 of Hess includes curved end struts 24 connected to associated curved struts 40. According to the Examiner, the connection points are offset from the center point of the curve and strut. Yet, the Examiner recognizes that each flexible link/wavy strip 40 shown in Figures 1 through 4 does not include the at least four curved segments connected together in series to three generally circumferential extending segments of approximately equal length.

The Examiner is reduced to referring to the sinusoidal wave connector as shown in Figures 12a and 12B of Hess. Somehow, the Examiner takes the sine wave, and associates it with the stent of Figure 4, and in this fashion asserts that the current claims are obvious.

However, in order to obtain the stent of claim 50, the Examiner also must necessarily modify the connector of Figure 12A and 12B. That is, because the connector in Figures 12A and 12B of Hess are described as a sine wave, in no way will that particular connector provide: a flexible length with at least four generally longitudinally extending curved segments; each having a proximal end and a distal end with a line joined the proximal ends of each

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curved segment being generally parallel to the longitudinal axis; and the curved segments being connected together in series by three generally circumferentially extending segments of approximately equal length.

Of course, this specifically describes the stent as seen in, for instance, Figure 6 or 8 of the current application. Naturally, it is specifically this aspect of the claim which renders the claim unobvious; that is, because there are generally straight segments which are parallel to the circumference to the circumferal direction of the stent, and longitudinally extending curved segments, attached by those circumferentially extending segments, the stent is rendered more flexible in any longitudinal direction, around any axis so that the stent can bend equally around any point off-set from its longitudinal axis.

There is no such explanation or use of this mechanism in Hess at all. In fact, of course, in Hess, one must look at Figures 1-4, substitute the connector of Figure 12, and modify that connector as in Figure 12, to meet the current claim. In this regard, Applicants respectfully assert that it would not be obvious to modify the Hess reference taken alone in order to find any of claims 50 and 53-54.

not straight

B. Are claims 51 and 52 obvious under 35 USC 103(a) as unpatentable over Hess in view of Richter?

According to the Examiner, when looking at Hess, each flexible link 40 of Hess "appears to be thinner" in each of the curved end struts. Of course, the Examiner has no such citation to any aspect of Hess to support that assertion. In fact, the Examiner indicates that he *recognizes* that the applicant might contend that Hess does not clearly teach a flexible wavy curved length with a width less than a thickness of each curved end strut.

So then, the Examiner directs the Applicants' attention to Richter. There, indeed, the connectors of Richter are sometimes formed to be thinner than the circumferential extending sections. This can best be seen for instance in Figure 2. However, once again, neither Richter nor Hess describes the particular circumferential connector as claimed in claim 50 and now modified by claim 51.

What the Applicants have created is a flexible link which is: less than the width of each curved end strut; where the flexible link contains the four generally longitudinally extending curved segments; each being generally connected together in series by the three generally circumferentially extending segments of approximately equal length.

Because it would not be apparent to the user to create the flexible links in the first place, it is respectfully asserted that it *clearly* would not be apparent to the user to modify those modified flexible lengths in order that they be less than the width of each curved end strut. In this fashion, it is respectfully submitted that claim 51 is not obvious in light of the references.

Turning to claim 52, the Examiner is presented with the modification wherein the ratio of the thickness to width of each flexible length is greater than $\frac{1}{10}$ 0.1. There is no such reference in either Richter or Hess. As well explained in the Applicants' specification, (for instance, at page 8, line 23 to page 9, line 4), this enhances the overall flexibility of the stent. Accordingly, because neither Hess nor Richter has in any way described this ratio, it is respectfully submitted that neither Hess nor Richter realized that this ratio was important. It is not a mere design modification, specifically for the reason that it is not well disclosed by any of the prior art references. In this fashion, it is respectfully submitted that claim 52 is also patentable in light of Hess in view of Richter.

C. Are all the claims 50 to 54 patentable as not obvious under 35 USC 103(a) over Richter '404 in view of Hess '035?

As well recognized by the Examiner in the most recent Office Action, the Richter reference does not have at least four curved segments as claimed. This, of course, is well laid out in the arguments above concerning the Hess reference. Of course, it is also well described that Hess does not have these elements. See, e.g., the analysis by the Examiner on page 3 lines 7 to 11.

Thus, in neither of the cited references can the Examiner find the specifically claimed element of the current claims. Accordingly, the Examiner can only use Richter and Hess with a modified connector (from Hess) in order to argue that the claims are rendered obvious. However, as previously explained, because the current connector enhances flexibility over and above any potential flexibility as described by the connector of Hess, it is respectfully submitted that his current combination of references cannot possibly accurately render obvious the current invention.

Accordingly, it is Applicants respectful contention that claims 50-54 are patentable over the Richter rejection in view of Hess.

For the same arguments as presented before, it respectfully submitted that claims 51, 52 and 54 would also not be rendered obvious independently by Richter in view of Hess. For instance, as previously described, there is no modification suggested in Richter or Hess to make the width of each flexible connector less than the end of each curved strut. There is no disclosure where

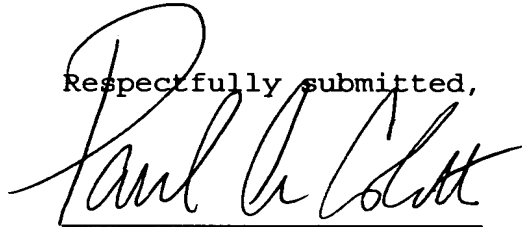
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the ratio of these widths are greater than 1.0. Further, there is no modification of Richter or Hess wherein the link is formed from the letter "N". Accordingly, it is respectfully submitted that claims 52 to 54 are patentable over the cited references.

CONCLUSION

Applicants herewith request a rapid allowance of claims 50 to 54.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Paul A. Coletti", written in black ink over a horizontal line.

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APPENDIX

50. A stent in the form of a generally tubular structure having a longitudinal axis, the stent comprising;

a plurality of circumferential sets of strut members that extend in a generally circumferential, ring-like pattern around the stent's longitudinal axis with each circumferential set of strut members comprising a plurality of curved end struts, the curved end struts being substantially curved across their entire length;

a plurality of flexible links with each flexible link being fixedly attached to two adjacent circumferential sets of strut members and each flexible link having a proximal end and a distal end with a line drawn through the proximal and distal ends of the flexible link lying transverse to the stent's longitudinal axis, each flexible link having at least four generally longitudinal extending curved segments that each have a proximal end and a distal end with a line joining the proximal end and distal end of each curved segment being generally parallel to the stent's longitudinal axis, the curved segments being connected together in series by three generally circumferentially extending segments of approximately equal length; and

the stent being further characterized by having the outermost curved segment of each flexible link connected to each curved end

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strut at a point thereon, the tangent to the curved end segment, at which point being at an acute angle with respect to the stent's longitudinal axis as taken in the direction of the curved end strut that is opposite the curved end strut onto which the outermost curved end segment is attached.

51. The stent of claim 50 wherein the width of the each flexible link is less than the width of each curved end strut.

52. The stent of claim 50 wherein the ratio of thickness to width of each flexible link is greater than 1.0.

53. The stent of claim 50 wherein the link is formed from stainless steel.

54. The stent of claim 50 wherein the link is formed in the shape of a letter "N".